

1706. Adulteration of flaxseed. U. S. v. 14 Barrels of Flax Seed. Default decree of condemnation and destruction. (F. D. C. No. 19101. Sample No. 35616-H.)

LIBEL FILED: February 12, 1946, Eastern District of Missouri; amended libel filed on or about March 5, 1946.

ALLEGED SHIPMENT: On or about October 13, 1945, by the Bisbee Linseed Co., from Chicago Heights, Ill.

PRODUCT: 14 barrels, each containing 250 pounds, of *flaxseed* at St. Louis, Mo.

LABEL, IN PART: "Pure Cleaned Flax Seed Kellogg & Miller Inc. Amsterdam, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: March 21, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF NONCERTIFIED COAL-TAR COLORS

1707. Adulteration of elixir phenobarbital. U. S. v. 95 Jugs of Elixir Phenobarbital. Default decree of condemnation and destruction. (F. D. C. No. 18635. Sample No. 5141-H.)

LIBEL FILED: December 7, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 15, 1945, by the Standard Drug Co., Inc., from Newark, N. J.

PRODUCT: 95 1-gallon jugs of *elixir phenobarbital* at Philadelphia, Pa.

LABEL, IN PART: "Elixir Phenobarbital Green * * * For use as a sedative and hypnotic."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained a coal-tar dye, Ext. D&C Blue #1, which is certified for use only in externally applied drugs and cosmetics.

DISPOSITION: January 10, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1708. Adulteration of phenobarbital tablets. U. S. v. 1 Package of Phenobarbital Tablets. Decree of condemnation and destruction. (F. D. C. No. 19212. Sample No. 12265-H.)

LIBEL FILED: February 18, 1946, District of Maine.

ALLEGED SHIPMENT: On or about September 18, 1945, by Moore & Co., Inc., from Worcester, Mass.

PRODUCT: 1 package containing approximately 98,000 *phenobarbital tablets* at Springvale, Maine. Examination of a sample disclosed that the product was colored with "methyl violet 4 RN," a coal-tar color which is not one that, according to regulations, may be certified as suitable for use in drugs.

LABEL, IN PART: "Compressed Tablets Purple Each Tablet Contains Phenobarbital ½ Gr."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article bore and contained, for purposes of coloring only, a coal-tar color that has not been listed for use in drugs in accordance with regulations and is other than one from a batch that has been certified.

DISPOSITION: March 8, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1709. Adulteration of redistilled water, and misbranding of posterior pituitary injection. Two indictments: U. S. v. E. S. Miller Laboratories, Inc. Pleas of nolo contendere. Fine of \$500 on each indictment. (F. D. C. Nos. 16539, 16588. Sample Nos. 62266-F, 27436-H.)

INDICTMENTS RETURNED: October 3, 1945, Southern District of California, against the E. S. Miller Laboratories, Inc., Los Angeles, Calif.

*See also Nos. 1702, 1703.

ALLEGED SHIPMENT: On or about November 13 and December 26, 1944, from the State of California into the States of Texas and Oregon.

NATURE OF CHARGE: *Redistilled water*, adulteration, Section 501 (b), the quality and purity of the article fell below the standard for *redistilled water* set forth in the National Formulary, an official compendium. The standard provides that *redistilled water* shall meet the requirements for clearness of ampul solutions set forth in the compendium, and that it shall meet the requirements of the pyrogen test set forth in the United States Pharmacopoeia. The article did not meet the requirements for clearness of ampul solutions since it was not clear but contained undissolved material, and it did not meet the requirements of the pyrogen test set forth in the United States Pharmacopoeia; and the difference in quality and purity of the article from the standard was not stated on its label.

Posterior pituitary injection, misbranding, Section 502 (a), the label statements, "Posterior Pituitary Injection * * * 20 U. S. P. Units per cc" and "Posterior Pituitary U. S. P. * * * each cubic centimeter contains 20 International Units," were false and misleading since they represented and suggested that each cubic centimeter of the article possessed a physiological activity equivalent to 20 U. S. P. posterior pituitary units. The article possessed a physiological activity of not more than 1.2 U. S. P. posterior pituitary units per cubic centimeter.

DISPOSITION: December 18, 1945. Pleas of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$500 on each indictment.

1710. Adulteration of triple distilled water. U. S. v. 224 Packages of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 17626. Sample No. 3655-H.)

LIBEL FILED: October 2, 1945, District of Maryland.

ALLEGED SHIPMENT: On or about August 9, 1945, from Brooklyn, N. Y., by E. Tosse and Co.

PRODUCT: 224 packages, each containing 10 ampuls, of *triple distilled water* at Baltimore, Md.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be both "Ampuls of Redistilled Water," the name of which is recognized in the National Formulary, and "Water for Injection," the name of which is recognized in the United States Pharmacopoeia, official compendiums, but its quality and purity fell below the standard set forth therein since it was contaminated with undissolved material.

DISPOSITION: November 7, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1711. Adulteration and misbranding of calcium gluconate. U. S. v. 11 Boxes of Calcium Gluconate. Default decree of condemnation. Product ordered delivered to the Federal Security Agency. (F. D. C. No. 18690. Sample No. 7678-H.)

LIBEL FILED: December 20, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about November 1, 1945, by the S. E. Massengill Co., from Bristol, Tenn.

PRODUCT: 11 boxes, each containing 25 ampuls, of *calcium gluconate* at New York, N. Y. Examination of a sample showed that the product contained, in addition to calcium gluconate, 0.9 percent of boric acid.

NATURE OF CHARGE: Adulteration, Section 501 (d), boric acid had been substituted in part for *calcium gluconate*.

Misbranding, Section 502 (a), the label designation, "Ampuls Calcium Gluconate," was misleading as applied to the article, which differed in the identity of its contained ingredients from that defined and described in the United States Pharmacopoeia under the title "Calcium Gluconate Ampuls."

DISPOSITION: February 6, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered for the use of the Federal Security Agency.